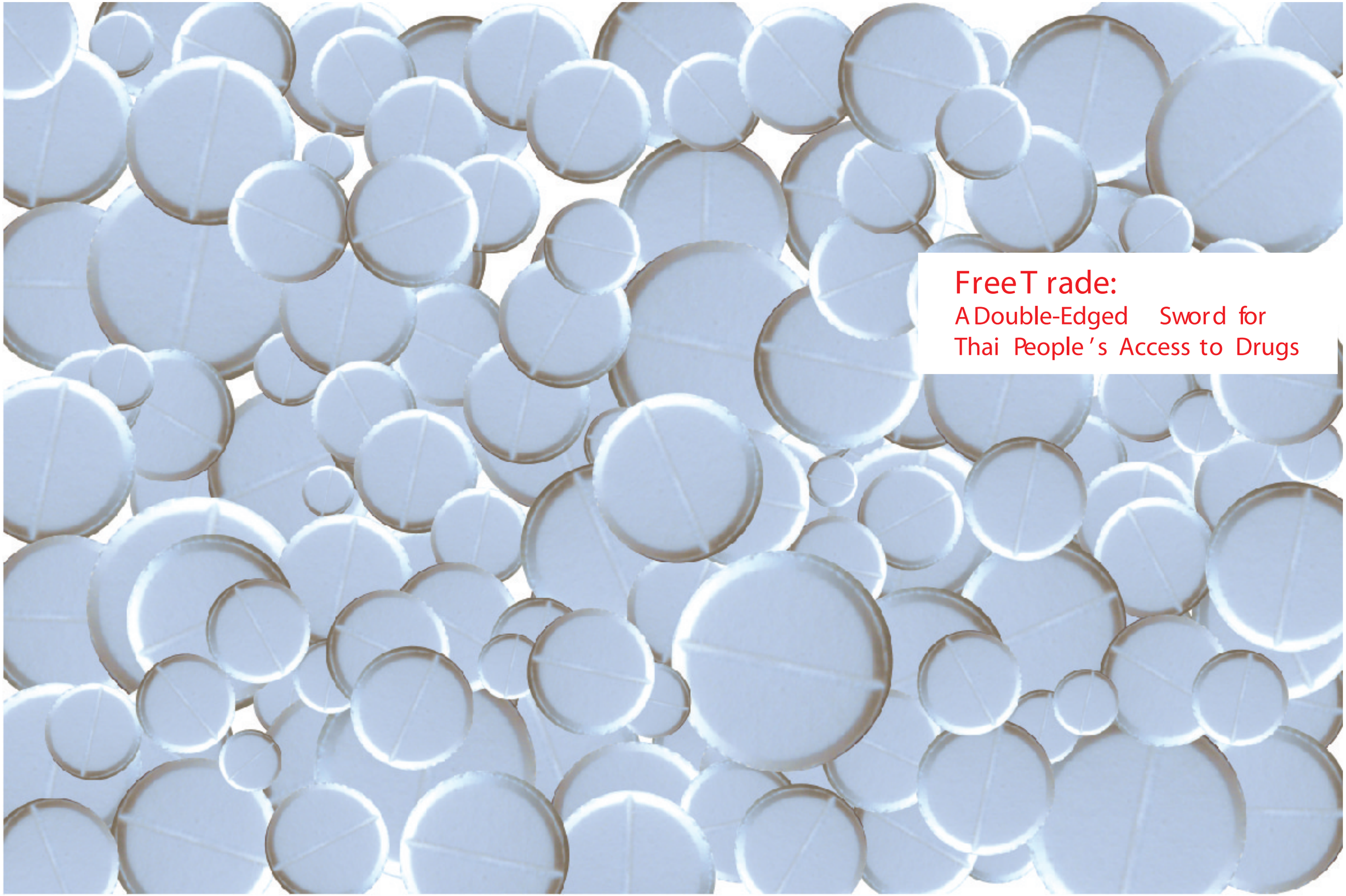

Free Trade:
A Double-Edged Sword for Thai People's Access to Drugs

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A Double-Edged Sword for Thai People's Access to Drugs

Free trade is a global trend bringing many benefits to economies and societies. But some people are asking how it will affect the health of Thais, especially their access to medicines.

Who wins and who loses from the intellectual property regime?

Medicines and free trade

Medicines are crucial for the maintenance of human life. But they are also goods that people produce and sell for profit, like the food we eat, the clothes we wear, the cars we drive, and countless other goods. Moreover, medicines are a high-technology product, requiring long periods and huge investments to develop.

Medicines are more than something used to extend human life, and are more than ordinary market goods. At present they are also assets that the owners can monopolize for themselves.

Rights to exclusive production and marketing of medicines, commonly known as patents, are an important part of the intellectual property system. They are at the core of the new trade rules that we refer to as free trade.

Rights to exclusive production and marketing imply the removal of competition from other producers. This generally implies higher prices that make medicines unaffordable for the poor in developing countries. The issue of medicines therefore needs to be examined together with the issue of free trade. How will Thai people's access to medicines be affected if Thailand enters a trade agreement with countries that are major producers and sellers of drugs, such as the United States?

That is the question that this article aims to answer.

1. Some Key Terms

Free trade—Trade between countries, governed by several agreements, i.e.,
Multilateral agreements—under the World Trade Organization
Regional agreements—organized by countries of the same region, and
Bilateral agreements—between two individual countries.

Patents—Legal rights, applying to 'products' such as medicines and to 'production processes'. These rights are awarded to those who invent the products or the production processes.

Access to medicine—Individuals' ability to obtain the medicines that they need.

Original medicines—Medicines based on original research and development. These are normally patented, so that no one can legally copy the medicine and compete with the patent owner for the duration of the patent.

Generic medicines—Medicines using the same active ingredients as original medicines. These are generally produced once the patents on the active ingredients expire.

The Development of Free Trade

The system that we now call 'free trade' has developed over many years. It is the result of attempts beginning after World War Two to improve and regulate international trade. Many countries agreed that the world economy was severely weakened by the war, and that measures needed to be taken to aid its recovery. These attempts led to the founding of organizations such as the International Monetary Fund (IMF), the World Bank, and the General Agreement on Trade and Tariffs (GATT).

GATT, which did not have the status of an organization, aimed to facilitate international trade in goods and services, by removing all obstacles to trade, such as tariffs, quotas, preferential access for certain countries, or health and environmental regulations. The free flow of goods and services was the main goal of GATT, and the ideal for many countries. The philosophy of free trade is associated with political liberalism, which grew markedly after World War Two.

From its inception in 1948, GATT organized many multilateral trade agreements, through numerous international meetings. GATT's last round of trade talks, the Uruguay Round, lasted from 1986 to 1994. On 1 January 1995, member countries agreed to move beyond GATT and established a global trade organization, called the World Trade Organization (WTO).

2. Thailand and the Free Trade System

At present the WTO has 148 members. Its main responsibilities are to set multilateral trade rules and to oversee the free trade movement among member countries.

In recent years, many regional agreements have been established. Examples are the North America Free Trade Agreement (NAFTA), and the ASEAN Free Trade Agreement (AFTA), of which Thailand is a member. Almost all of the countries involved in these agreements, including Thailand, are also members of the WTO.

All members of the WTO have a single vote, regardless of their size. This, together with the rule that all proposals have to be adopted by consensus, has increased the bargaining power of developing countries, and made it more difficult for powerful countries to impose their wishes.

In response, some developed countries such as the United States have complained about the difficulty of reaching agreements in the WTO. They have instead been pursuing bilateral Free Trade Agreements (FTAs) with individual trading partners. At present the United States is negotiating with many countries, including Thailand. This tendency became much more pronounced after the WTO meeting in Seattle in 1999, where trade talks collapsed.

At present Thailand is a member of three types of trade agreement. It has been a member of the World Trade Organization since its establishment in 1995. As a member of the Association of Southeast Asian Nations, or ASEAN, it belongs to the ASEAN Free Trade Agreement (AFTA), founded in 1992. Thailand signed a free trade agreement with China in 2003, with India and Australia in 2004, and with New Zealand in 2005. It also signed an agreement with Bahrain in 2002, but the agreement has not yet come into effect. Thailand is currently negotiating bilateral trade agreements with the United States, Japan, Peru, and countries in the BIMST-EC group, which is comprised of Bangladesh, the Maldives, Myanmar, Sri Lanka, Thailand, Nepal, Bhutan, and India (though India already has an agreement—see Figure 1.)

To carry out these negotiations, the Thai government has set up three working groups (see Figure 2). There are several Negotiation Groups, each responsible for negotiating with a designated country such as Australia and Japan. There is also one Strategy Coordination Group that coordinates the Negotiation Groups and the Monitoring Group overseeing the impacts of negotiation.

3 Thailand's Strategy for Choosing Partners for Trade Agreements

- Large countries with important markets, such as the United States and Japan
- Countries with potential for trade expansion, such as China, India, Australia, and New Zealand
- Countries that act as doorways to their region, such as Peru in Latin America, Bahrain in the Middle East, and the BIMST-EC countries (Bangladesh, India, Myanmar, Maldives, Sri Lanka, Nepal, and Bhutan) in South Asia

Bilateral trade agreements are not supposed to contravene the rules of the WTO. These agreements are therefore like smaller and more advanced versions of the multilateral agreements.

There are therefore three connecting levels of trade agreement: multilateral agreements under the WTO, regional agreements between neighboring countries of the same region such as AFTA, and bilateral agreements such as the ones between Thailand and China, and Thailand and Australia.

Figure 1: Countries negotiating trade agreements with Thailand

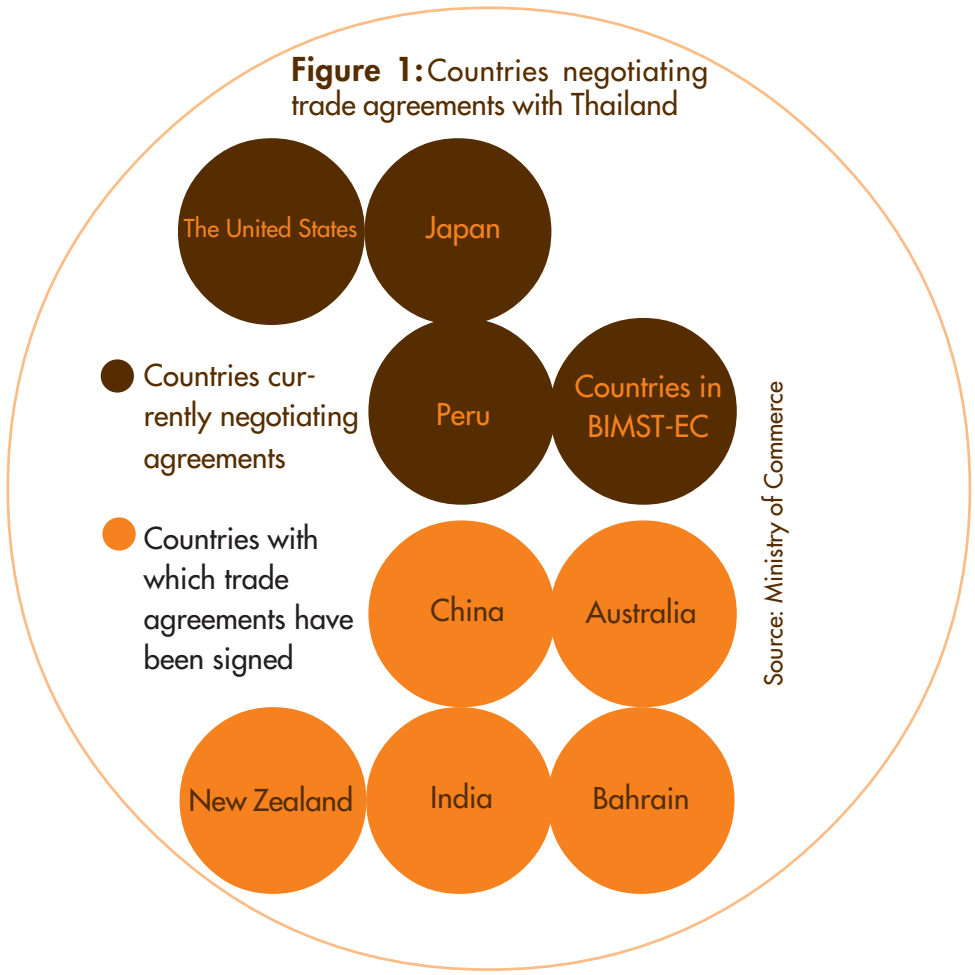
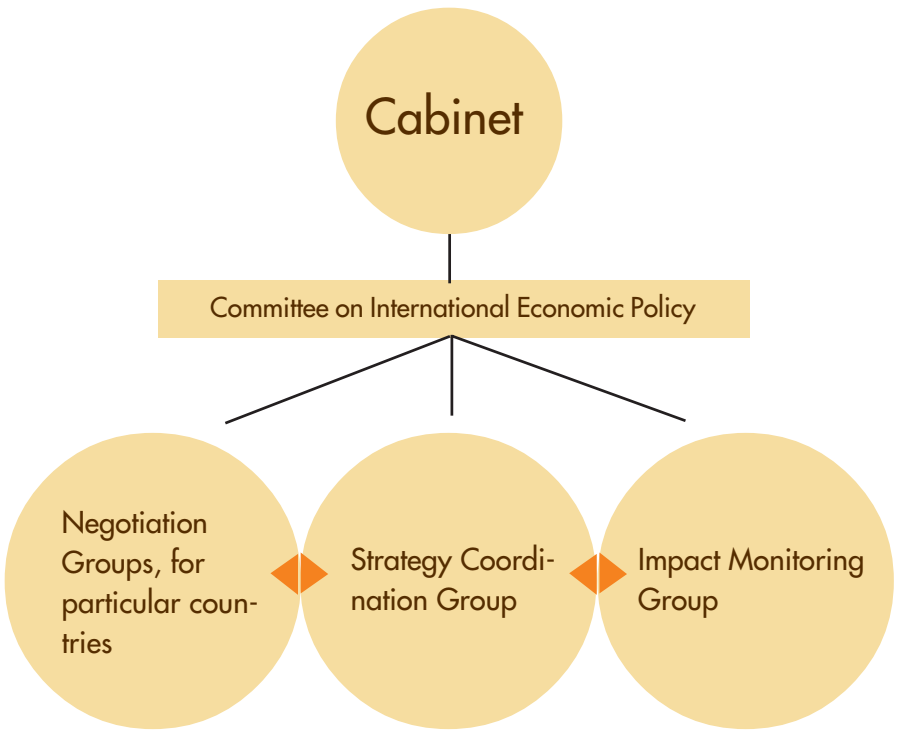


Figure 2: The framework for free trade negotiations with other countries



Source: Department for International Trade Negotiations, Ministry of Commerce

Why do we need free trade?

International trade is an important source of income. In 2003, for example, 54% of Thailand's Gross Domestic Product (GDP) came from exports. A large proportion of the money used to develop the Thai economy and Thai society comes from selling goods abroad.

Thai history since the Ayutthya period shows that whenever international trade is flourishing, the country makes social and economic progress. Whenever trade is limited, the country stagnates. For instance, in the 170 year period from the 1670s to the 1840s there was little trade with the outside world, and the country made little economic progress. After the Bowring Treaty between England and Thailand was signed in 1846, international trade increased markedly, and the economy and the country developed enormously.

Free trade depends on coordination at the global level, to eliminate unfair barriers against the free flow of goods. Any country that is a member of the WTO is supposed to be able to trade with any other, with no or minimal barriers. These barriers include tariffs, quotas, or health and environmental regulations. Goods from countries that are members of the WTO can out-compete goods from countries that are not members, because goods from non-members face greater barriers.

Some countries therefore complain that they have no choice but to join the WTO, because otherwise they would suffer many negative effects. First, they would lose the opportunity to influence the WTO regulations. Second, they would miss out on trade opportunities. Third, they would be less competitive compared to countries that are members.

At the same time, the WTO process can benefit some groups at the expense of others. For instance, local producers can suffer if forced to compete with cheaper imports, though local consumers benefit from lower prices. The outcomes depend on how countries respond to the opportunities presented by free trade.

Economic growth is connected with the expansion of international trade, which increases countries' incomes. Increased income allows countries to pay their public debts, and to have more resources for social investment, including health.

Concrete evidence of this comes from the period of rapid growth in Thailand between 1987 and 1997. Income earned from overseas permitted Thailand to lower its public debts from 25 percent of national budget in 1987 to 5 percent in 1997. Expenditure on health increased from 4 percent of GDP to 7 percent. It was therefore possible to substantially improve the coverage and quality of rural health facilities. This was an important foundation for improvements in health.

Agreements and mechanisms that facilitate free trade

There are three fundamental agreements under the WTO:

- The General Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This is the agreement that will have the most effect on the pharmaceutical trade in Thailand, and it is examined in detail below.

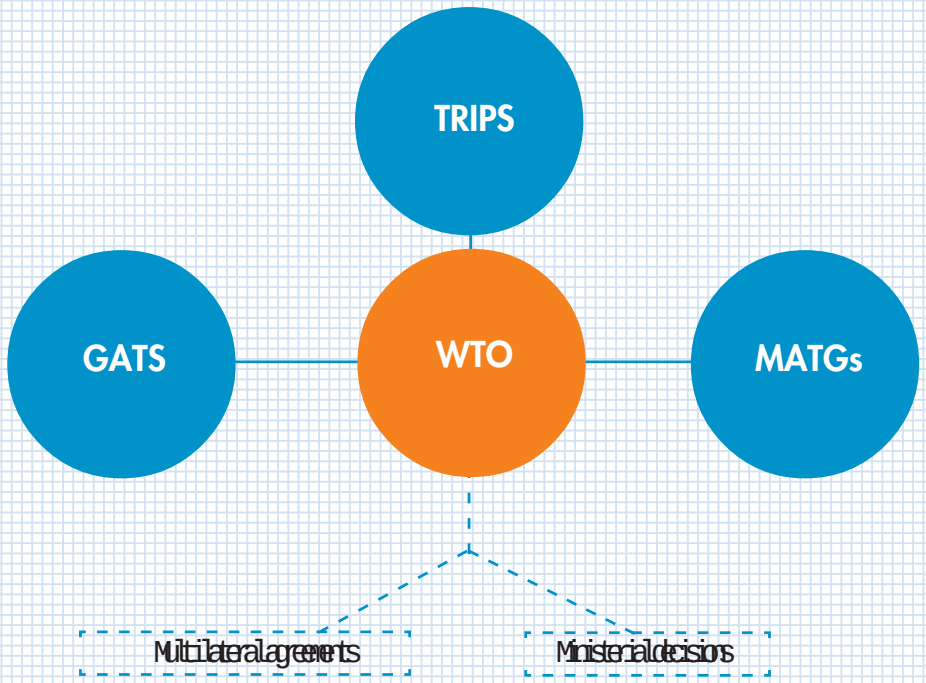
- The Multilateral Agreement on Trade in Goods (MATGs) is relevant to health in various ways, such as the sanitary measures related to plants and animals, and measures on technical barriers to trade.

- The General Agreement on Trade in Services (GATS) which includes health related services as well as movements of health professionals.

Free trade negotiations can be thought of as a tricycle, with TRIPS as the front wheel, and MATGs and GATS the two back wheels, and the WTO as the driver. The WTO organizes meetings of ministers every two years to make important decisions and to formally accept decisions that are made (see Figure 3).

Negotiation of Free Trade Agreements at the regional and bilateral level rests on the same principles, though bilateral and regional negotiations are more advanced than the WTO agreements and will be the driving force to move the WTO negotiation towards more free trade.

Figure 3: Agreements and mechanisms that the WTO uses to facilitate international trade



The General Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The General Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is one of the key mechanisms for regulating world trade, and a major factor affecting access to drugs. TRIPS grew out of the Uruguay Round of GATT, before the establishment of the WTO. TRIPS has seven parts and 73 articles.

The most important feature of TRIPS is that it requires member countries to introduce laws protecting intellectual property rights, in line with TRIPS standards.

Intellectual property rights cover all types of inventions: they cover industrial products, natural products, works of art, models, computer software, production processes, and brands.

TRIPS protects intellectual property rights in many ways. For medicines, the most important mechanism is patents. Both products and production processes can be patented.

Patents give the holder the right to sole production or use for a suitable period, as a way of rewarding innovation and to give the inventor an incentive to make the discovery public.

The right to sole production or use means that no one else may manufacture, import, or distribute a product, or use a production process, without receiving permission from the patent owner. These rights do, however, have a legal time limit. Under TRIPS this limit is 20 years from the day when the patent is filed with the relevant authority.

The objective of patents, besides providing a reward for the inventor, is to create benefits for society. The intention is to give people an incentive to work hard to develop new products and processes. **The underlying principle is that the rewards received by the individual inventors and the social benefits from the invention need to be balanced.**

TRIPS lays out some basic rules on the protection of intellectual property through patents. The key TRIPS' rules governing intellectual property protection in international trade are summarized in Box 4.

4. Fundamental TRIPS Rules on Using Patents to Protect Intellectual Property

- Patents can apply to production processes and to products. For instance, pharmaceutical research may result in new compounds or in new manufacturing methods, and both of these can be patented.
- Inventions covered by the framework must be (1) original, such as a medicine that has never previously been produced; (2) close to completion and clearly specified; and (3) capable of industrial production.
- Protection lasts for at least 20 years, from the day that the patent is filed with relevant authority.
- All types of invention receive equal treatment, regardless of whether they originated in the country concerned or in another country.
- Applications for patents must provide detailed and complete information on the invention, including production methods. This information must be made public.
- Member countries may reserve the right not to observe patents in the following circumstances:
  (1) the invention has adverse effects on health or morality;
  (2) the patent is for the diagnosis or treatment of illnesses, or a surgical technique;
  (3) the patent is for a plant or animal (other than a microbe) or biological processes for the production of plants or animals (other than processes for the production of microbes). If a country wishes to protect a particular plant or animal, it may do so using specific legislation. It does not necessarily have to grant a patent.

> “Thailand’s patent laws were consistent with TRIPS three years before TRIPS was created, and eight years before the deadline for implementation”

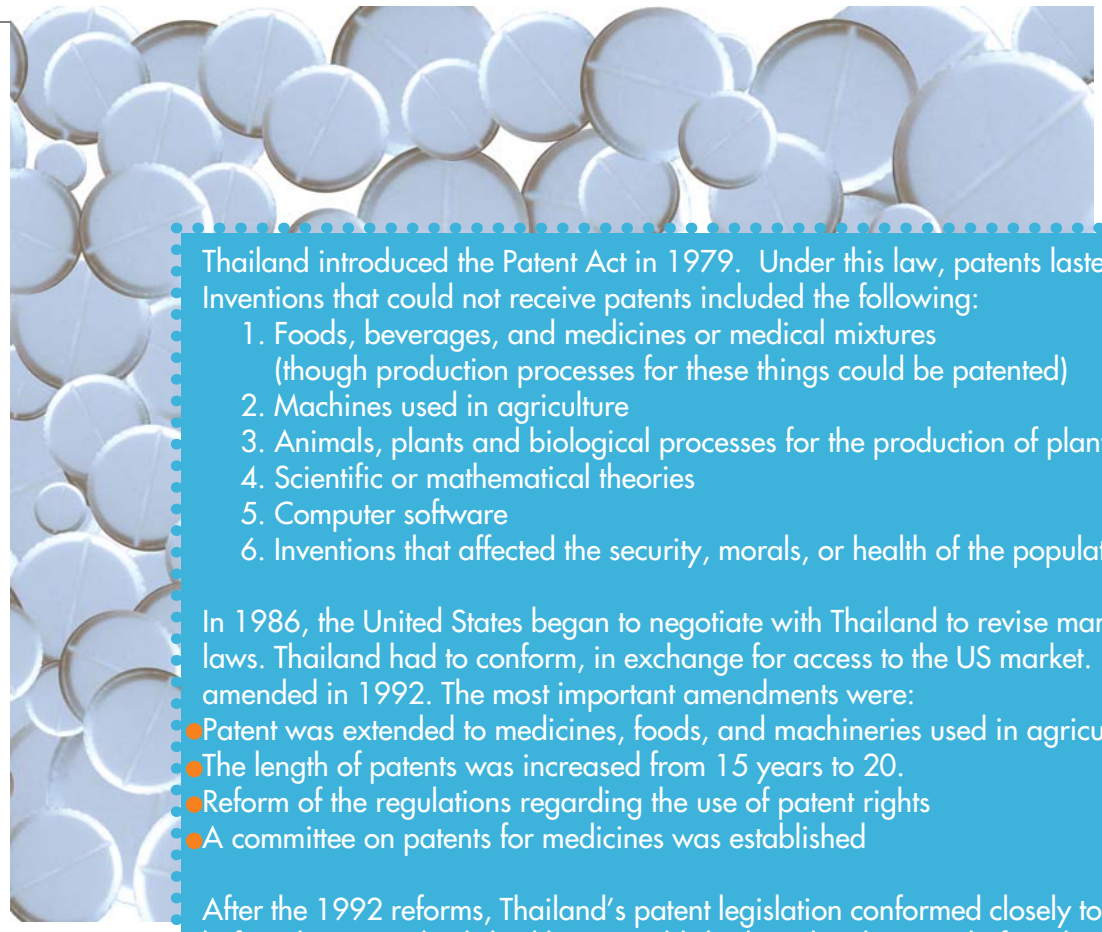
The WTO has required that countries implement TRIPS, on the grounds that it is a fundamental agreement. Different countries have different deadlines for implementing the agreement, depending on their income level.

- Developed countries are supposed to revise their laws consistent with TRIPS within one year after January 1st, 1995, the date that TRIPS came into effect.
- Developing countries have 5 years to revise their laws, or until January 1st 2000.
- The least developed countries have 11 years, or until January 1st 2006. If necessary this deadline can be extended. (Implementation of the rules for patenting medicines can be extended for 21 years, until 2016.)

Thailand is defined as a developing country. It had the patent law since 1979 which allowed only the ‘production process’, and not the ‘product’, to be protected. Thailand’s patent law was reformed to conform to international standards in 1992, **eight years before the TRIPS deadline.**

In other words, Thailand’s patent laws were consistent with TRIPS three years before TRIPS was created, and eight years before the deadline for implementation (see Box 5). This was a result of pressure from the United States. The United States applies the same sort of pressure when it makes free trade agreements. It persuades countries to adopt conditions in bilateral agreements that it will later be proposed in multilateral negotiation forum.

TRIPS clearly states that violation of the rules can lead to punishment in the form of trade sanctions, which can have a severe effect on the economy.



5. Thailand's Patent Laws

Thailand introduced the Patent Act in 1979. Under this law, patents lasted 15 years. Inventions that could not receive patents included the following:

1. Foods, beverages, and medicines or medical mixtures (though production processes for these things could be patented)
2. Machines used in agriculture
3. Animals, plants and biological processes for the production of plants and animals
4. Scientific or mathematical theories
5. Computer software
6. Inventions that affected the security, morals, or health of the population

In 1986, the United States began to negotiate with Thailand to revise many of its laws, including its patent laws. Thailand had to conform, in exchange for access to the US market. Thailand's patent laws were amended in 1992. The most important amendments were:

- Patent was extended to medicines, foods, and machineries used in agriculture
- The length of patents was increased from 15 years to 20.
- Reform of the regulations regarding the use of patent rights
- A committee on patents for medicines was established

After the 1992 reforms, Thailand's patent legislation conformed closely to WTO standards, three years before these standards had been established, and eight years before the deadline for conforming to them.

In 1999, the law changed one more time to disband the committee for patents on medicines, and to begin using the petty patent system. This revision was also based on trade negotiations with the US and to make the Thai system fully consistent with TRIPS.

Flexibilities under TRIPS to promote access to medicines

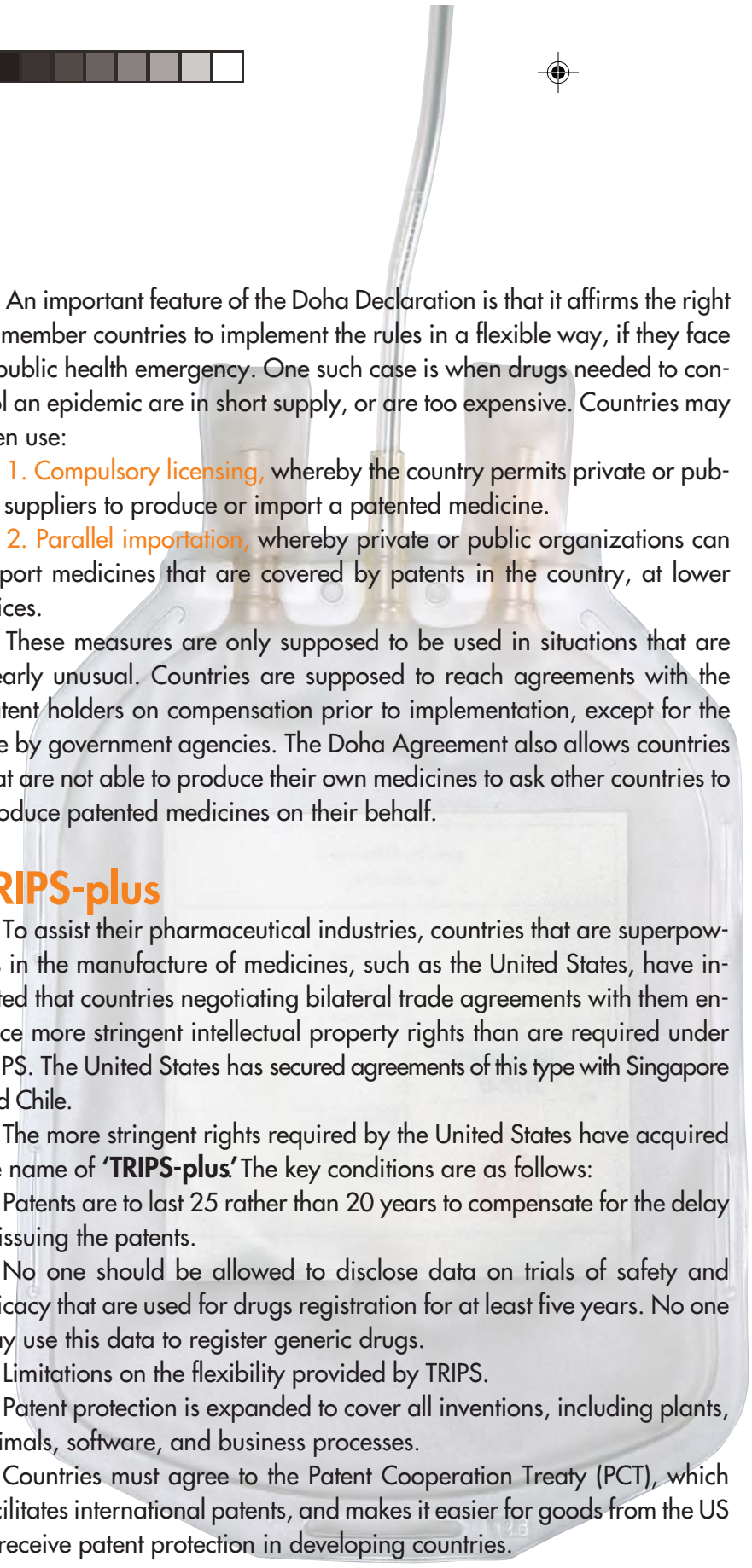
Although there are certain flexibilities under TRIPS to protect human health, such as parallel imports and compulsory licensing, they were not well recognized and implemented. Developing countries, and the least developed countries, expressed concern about the effect of TRIPS on their populations' health, because of the enforcement of intellectual property rights. This became a major issue at the ministerial meeting of the WTO in Doha, Qatar, in 2001. This meeting issued a Declaration on the TRIPS Agreement and Public Health (sometimes known as the Doha Declaration).

The key point of the Doha Declaration was that there should be flexibility in the enforcement of TRIPS with regard to patents on medicines. The aim is to reduce any possible adverse effects on health in poor countries (see Box 6).

6. The Doha Declaration on the TRIPS Agreement and Public Health

The main points of the Doha Declaration on the TRIPS Agreement and Public Health are:

- **TRIPS does not prevent, and should not prevent, member countries from taking any measures to protect the health of their populations.**
- **The implementation of TRIPS must uphold the right of member countries to protect the health of their populations.**
- **In particular, it must promote access to medicines.**
- **TRIPS recognizes the right of countries to implement the rules in a flexible way, to protect health. This includes the right to flexibility in the face of public health emergencies.**
- **Countries can make their own decisions on when to exercise their right to flexibility. However, the rights should be exercised when there is a compelling reason to do so. The epidemics of HIV/AIDS, malaria, and tuberculosis represent such reasons. Countries can exercise their rights without jeopardizing the principle of Most Favored Nation, and that of National Treatment.**



An important feature of the Doha Declaration is that it affirms the right of member countries to implement the rules in a flexible way, if they face a public health emergency. One such case is when drugs needed to control an epidemic are in short supply, or are too expensive. Countries may then use:

1. Compulsory licensing, whereby the country permits private or public suppliers to produce or import a patented medicine.

2. Parallel importation, whereby private or public organizations can import medicines that are covered by patents in the country, at lower prices.

These measures are only supposed to be used in situations that are clearly unusual. Countries are supposed to reach agreements with the patent holders on compensation prior to implementation, except for the use by government agencies. The Doha Agreement also allows countries that are not able to produce their own medicines to ask other countries to produce patented medicines on their behalf.

TRIPS-plus

To assist their pharmaceutical industries, countries that are superpowers in the manufacture of medicines, such as the United States, have insisted that countries negotiating bilateral trade agreements with them enforce more stringent intellectual property rights than are required under TRIPS. The United States has secured agreements of this type with Singapore and Chile.

The more stringent rights required by the United States have acquired the name of **'TRIPS-plus'**. The key conditions are as follows:

- Patents are to last 25 rather than 20 years to compensate for the delay in issuing the patents.
- No one should be allowed to disclose data on trials of safety and efficacy that are used for drugs registration for at least five years. No one may use this data to register generic drugs.
- Limitations on the flexibility provided by TRIPS.
- Patent protection is expanded to cover all inventions, including plants, animals, software, and business processes.
- Countries must agree to the Patent Cooperation Treaty (PCT), which facilitates international patents, and makes it easier for goods from the US to receive patent protection in developing countries.

The US proposals (known as TRIPS-plus) have major implications for access to drugs, because they raise the price of patented drugs, and restrict competition for longer period. If Thailand agrees to these conditions, they will adversely affect people, particularly the poor. In addition, national health insurance programs such as the Thirty Baht Scheme (in which all visits to government facilities cost only 30 baht), and schemes for the universal access to HIV/AIDS drugs will inevitably be affected.

"A patent is like an invisible **'immunity'** that keeps prices high until it expires. If there are two medicines, with same demand, equal development, production, and marketing costs, one of which has a patent and the other does not, the patented drug will be more expensive, and will remain more expensive as long as the patent applies."

> Receiving a patent is like receiving the ability to maintain a complete monopoly

How does free trade increase the price of medicines?

There are several fundamental factors determining the price of medicine. The first is investment in research and production. The second is marketing. A less obvious factor, though one that is extremely important, is patents. This right to exclusive production and marketing reduces competition and raises prices. A patent is like an invisible 'immunity' that keeps prices high until it expires. If there are two medicines, with same demand, equal development, production, and marketing costs, one of which has a patent and the other does not, the patented drug will be more expensive, and will remain more expensive as long as the patent applies.

Many analysts agree that a feature of free trade that can keep prices high, and can affect access to medicines in developed and developing countries, is over-protection of intellectual property rights. TRIPS-plus is an example of over-protection.

Rights to sole production

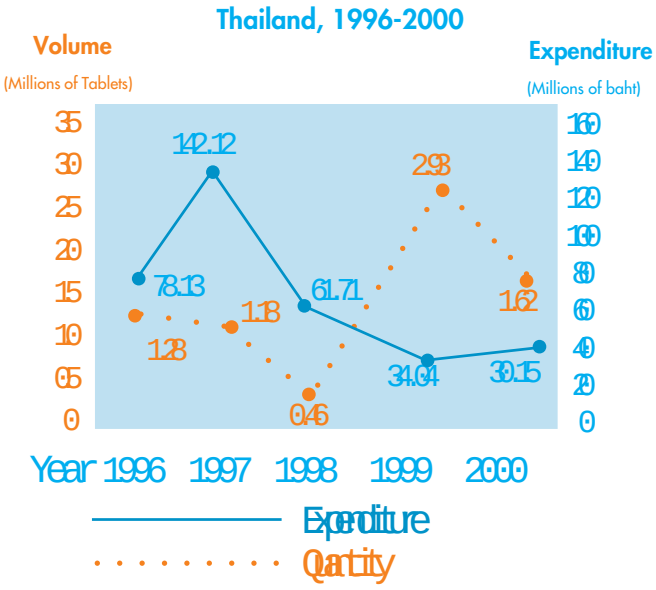
TRIPS, TRIPS-plus, and all other patent regulations, give the patent owners the right to sole production and marketing. For the duration of the patent, no competitors are allowed to produce the same good, or use the same production process. **Receiving a patent is like receiving the ability to maintain a complete monopoly.**

Owners who have complete monopolies can charge as high a price as they want, and as high as the market will bear. It is therefore not surprising that drugs covered by patents (original drugs) have the highest prices. These high prices affect access to drugs in both developed and developing countries.

The following data and research result confirm the above conclusion:

1. The anti-fungal drug Fluconazole is a good example of how patents increase the price of medicine and restrict access. Between 1996-1998, when it did not yet have a generic competitor, Fluconazole was expensive and its use was restricted. But in 1999, when a generic drug became available, expenditure on Fluconazole dropped by almost half, and usage increased six times (Figure 4).

Figure 4: Expenditures and volumes of *Fluconazole* in Thailand, 1996-2000



Source: Thai Health Profile 1999-2000

Table 1: Comparison of wholesale prices for medicines that once had patents and medicines that never had patents

Type of drug and generic name	Price of original drug (baht per tablet)	Price of generic drug (baht per tablet)	Price difference (original / generic)
Antibiotic			
Rifampicin 300 mg	16.0 / Rifadin	2.6	6.2
Diabetes			
Glibenclamine 5 mg	2.9 / Daonil®	0.2	14.5
Glipizide 5 mg	4.0 / Minidiab®	0.4	10.0
Metformin 500 mg	2.3 / Glucophage®	0.3	7.7
Asthma			
Salbutamol MDI 200 puff	139.1 / Ventolin®inhaler	83.5	1.7
Terbutaline 2.5 mg	2.2 / Brycanyl®	0.8	2.8
Budesonide MDI 200 / puff	354.2 / 100 puff / Pulmicort®	250 / 200 puff	2.8

Source: Adapted from Raksaworn Chaisa-art and Nusaraporn Kessomboon, 2004.

2. Raksaworn Chaisa-art and Nusaraporn Kessomboon of the Faculty of Pharmaceutical Science, Khon Kaen University, have compared the prices of original drugs and generic drugs for a number of illnesses, such as infectious diseases, diabetes, and asthma. They found that the original medicines were 1.7-14.5 times more expensive than the generic drugs, as can be seen in Table 1.

3. Jiraporn Limpananond and colleagues, from the Faculty of Pharmaceutical Sciences, Chulalongkorn University, examined the market price of the HIV/AIDS drug group NRTI in Thailand in the period 2001-2004. The cost of the brand name form of the original drug ATZ+3TC was around 140 baht while the cost of the generic was 25 baht. The brand name form of the drug d4T 40mg was 90 baht while the generic was 10 baht.

4. Similarly, UNAIDS compared the price of antiretroviral drugs that were covered by patents with those that are not in the period 1996-2000. They found that the price of patented drugs fell by 20 percent over this period, while the price of non-patented drugs fell by 60-90 percent.

Affordable medicines: But only old ones

Under TRIPS, patents last for 20 years from the day they were filed for registration. Thai patent laws have used a 20-year rule since the year 1992, or 8 years before TRIPS deadline. Patented medicines only face competition once the patent has expired.

However, in practice pharmaceutical companies have to spend long periods carrying out research and developing drugs before they can bring them to market. This can take 8-12 years from the time when the patent is filed. Competition is therefore generally restricted for less than 20 years, depending on the length of the research and development process.

However, in negotiations for a free trade agreement with Thailand, the United States is requesting that Thailand conform to the TRIPS-plus rules. If Thailand agrees to these requests, as Singapore and Chile did in their negotiations, then market exclusivity can be extended by up to five years.

The 8-12 year wait means that many drugs can be considered 'old' by the time the patents expire. This is both good and bad. It gives doctors time to accumulate experience with the drug, and learn about side effects. On the other hand, it may mean that the drug is out-of-date, so that health professionals will not use it. Health professionals, with intensive marketing from the drug companies, will prefer to use more recent drugs, even if they are still covered by patents and are more expensive.

> “only about one quarter of the original drugs were subsequently produced as generics”

Wait for a long time, but without much hope

Even if people wait for 8-12 years for the patent to expire, there are two reasons why they might not be able to obtain cheap generic drugs.

First, drug companies make minor modifications to existing drugs and then claim that these drugs are ‘new’, and therefore qualified for patents. When Jiraporn Limpanond and colleagues examined patent applications in Thailand in the period 1992-2002 they found that companies used many methods for extending the life of market exclusivity.

- Companies would claim that the drug could be used to treat a different condition from the original one.
- Companies would claim that a new way of using the drug had been discovered: for instance, taking the drug two times a day rather than three.
- Companies would combine two drugs for which the patents had expired, or were about to expire, and claim that the combination represented a new drug.

Limpananond and colleagues found that 72 percent of drugs registered in Thailand in the years 1992-2002 belonged to one of these three categories.

The other reason that people may not be able to obtain cheap generics after the original patent has expired is that Thai factories do not produce them. One study showed that 7 years after the original products appeared in the market, in 1986-1990, only about one quarter of the original drugs were subsequently produced as generics. There were three main reasons for this:

1. Size of the market. Factories only produce generic drugs that have big market.
2. Production technology. Some medicines require more advanced technology than is available in Thailand, particularly vaccines.
3. Raw materials. Most raw materials used to produce drugs have to be imported. Some are very expensive. Companies may not be interested in producing such drugs because they may not be able to recoup their investment.

In summary, improving access by producing generic versions of brand name drugs is not always easy. The decision to produce a generic version depends on the potential producers and on the market. Only some brand name drugs are in fact produced as generics, which limits people’s access to medicine.

Who is affected?

TRIPS and TRIPS-plus raise the price of medicines, which affects everyone who has to use medicines, particularly medicines that are covered by patents. **The effect is perhaps not restricted to this group, but extends to the patients' families and to society. It affects health insurance programs, such as the Thirty Baht Scheme, the Social Welfare Scheme, and Civil Service Medical Benefits Scheme, as well as hospitals and other health facilities.**

However, because only some drugs are patented, and because patented drugs tend to be for new or chronic illnesses such as HIV/AIDS, tuberculosis, malaria, diabetes, hypertension, heart diseases, cancer, and asthma, people with these diseases are affected the most. This group is very large: for instance, at least 600,000 Thais have HIV/AIDS.

People with low incomes are particularly vulnerable: Statistics for 2003 show that there were 1.5 million poor households in Thailand (out of a total of 16 million), containing 6 million individuals, or 10 percent of the total Thai population.

Poor people are disadvantaged in every way, but particularly health. It is said that 'poverty and poor health go together.' If free trade raises the price of medicines because of increased protection of intellectual property, the health of the poor will suffer.

At present, poor people, particularly in rural areas, depend heavily on the Thirty Baht Scheme, as well as the Social Welfare Scheme and the Civil Servants Medical Benefits Scheme. These schemes may be threatened by higher drug prices.

Effects on health insurance schemes: The effect of patents on the Thirty Baht Scheme is particularly noteworthy, because the scheme is new, and not yet completely secure. Hospitals are already experiencing financial problems because the revenue they receive under Thirty Baht Scheme does not reflect their true costs. If Thailand does agree to TRIPS-plus, as the United States demands, then the financial problems will become even more severe, particularly in the long run. TRIPS-plus extends the length of patents by up to five years, and restricts the conditions under which countries can over-ride patents. Expenditures under the Thirty Baht Scheme will therefore increase in the future.

> "TRIPS and TRIPS-plus raise the price of medicines, which affects everyone who has to use medicines, particularly medicines that are covered by patents"

The problem will be particularly severe if the government includes HIV/AIDS medicines under the Thirty Baht Scheme, as it has recently suggested. It will further complicate the already-difficult financial problem and thus make the situation more difficult to deal with.

Effects on programs to supply anti-retroviral drugs: The impact of free trade on efforts to provide anti-retroviral drugs to people with HIV/AIDS has received substantial attention, in Thailand and overseas. Most commentators have argued that if Thailand signs a free trade agreement with the United States, and the agreement includes TRIPS-plus, then the program to distribute anti-retroviral drugs would be adversely affected.

People using anti-retrovirals need to take them every day for the rest of their lives. Some people eventually have to change to different, more expensive medicines, because of side effects or drug resistance. The longer people take the drugs, the more often they need to change. The new medicines are always patented and expensive. The cost of the anti-retroviral program is therefore high and unpredictable.

At present, approximately 57,000 of the 600,000 people with HIV/AIDS in Thailand receive anti-retroviral drugs (data from the Department for Disease Control, January 2005). These 57,000 people represent about one third of the number who should be taking anti-retrovirals — that is, people whose CD4 count is below 200 cells per milliliter or who have opportunistic infections.

The National Anti-retroviral Drugs Program, run by the Ministry of Public Health, has three drug regimes, with different costs, as summarized in Table 2.

Even using the cheapest drug regime shown in Table 2, the annual cost of treating 57,000 people is 820 million baht. If the Thai government expands coverage to include everyone who would benefit, the cost would be billions of baht. Oxfam, a non-governmental organization based in U.K., has calculated that if the government were to provide the cheapest possible treatment (costing 40 baht per person per day) to everyone who needed it, the cost would be at least 2 billion baht per year.

The reason the Thai government is able to provide anti-AIDS drugs is because the Government Pharmaceutical Organization produces certain generic drugs itself. Even though these are first line drugs, the drugs produced by the Government Pharmaceutical Organization are still about 10 times cheaper than brand name drugs. These drugs do not have patent protection in Thailand, because they were already produced locally or imported before the revision of the patent laws in 1992. (Before 1992, medicines could not be patented in Thailand.) Since 1992, most anti-AIDS drugs have had patent protection, and it has been difficult to produce generics.

If a free trade deal is signed as is proposed by the US, the future production of new drugs for people with HIV/AIDS may become more difficult. The extended patent period, data exclusivity and limits to the flexibility provided by TRIPS will delay the production of lower-price generic anti-retrovirals.

Table 2: Approximate costs per month of HIV/AIDS medication

Drug regimen	Indications	Average cost (baht per person per month)	Notes
1	Has not previously received anti-retroviral	1,200	Generic drugs produced in Thailand
2	Has followed regime 1, and has started to experience problems	2,700	Thai and imported drugs
3	Has followed regime 2, and has started to experience problems	5,300	Thai and imported brand name drugs

Under this circumstance, there are only limited options. One possible option is to resort to the flexibility provided by the TRIPS, namely using compulsory licensing or parallel importation (see Box 6). This option, however, must be based on national legislation. Even then, it is not without difficulty. When South Africa and Brazil passed the legislation for this purpose, they were taken to court by international pharmaceutical companies and the United States, the world's pharmaceutical superpower (see Box 7). Even though the drug companies and the US eventually dropped the case, it did demonstrate that compulsory licensing and parallel importation are not easy options.

At present Thailand has the law to support the use of compulsory licensing and parallel importation if needed, but if the government agrees to the TRIPS-plus requirements, it has to revise the patent act to limit the implementation of these measures.

7. The Experiences of South Africa and Brazil

South Africa and Brazil were both taken to court by drug companies when they introduced compulsory licensing and parallel importation of AIDS medication that would otherwise have been too expensive.

In South Africa, anti-AIDS drugs were covered by patents and were very expensive. The country therefore promulgated a law on drugs and related products in 1997, giving the government the power to buy cheaper medicines from overseas, even if the medicines were protected by patents in South Africa.

The United States took South Africa to the WTO, arguing that South Africa had violated the rules on intellectual property. It also blacklisted South Africa, as a country requiring special attention regarding trade. In May 2001, after negotiations with South Africa had broken down, 39 international drug companies took South Africa to court, for violating patent law.

During the court case, some companies reduced the price of medicines in order to preserve the market. The price of medicines previously costing $10,000 per year was reduced to $1,000 per year. However, even this reduced price was too high for people with the virus. If the same drugs were imported from India, the price was $295 per year.

Before the case was concluded, the drug companies decided to withdraw, and South Africa agreed to conform to TRIPS rules.

Brazil had a similar experience to South Africa. The government had a policy of providing AIDS drugs to all people with the disease. The two drugs it needed were Efavirenz and Nelfinavir, both of which were covered by patents and were very expensive. Brazil negotiated with the drug companies to reduce the price, but was unsuccessful. The government therefore instructed the government pharmaceutical agency to produce the two drugs through compulsory licensing.

The owner of the patents protested to the Brazilian government. The Pharmaceutical Research and Manufacturers of America, a powerful lobby group for the pharmaceutical industry, argued that the Brazil should no longer receive reduced tariffs, and the US government took Brazil to the WTO. The US case did not refer to the medicines themselves, but to a law on industrial products that Brazil passed in 1996. The law stated that companies holding patents to any type of good should produce that good in Brazil within three years, or else the government would permit other companies to produce the good or import it from the cheapest available source, regardless of patents.

The United States dropped this case, like the South African case, because of international pressure.

The effects are similar for developed and developing countries

It would be wrong to assume that free trade will only affect access to medicines in developing countries. Even in developed countries such as the United States and Australia, there is an impact on access.

Even though the United States is a pharmaceutical superpower, its strict patent laws make American medicines excessively expensive, and reduce Americans' access. This is particularly true for people on low and middle incomes.

When elderly Americans visit Canada, they often buy medicines to take home, because medicines are cheaper in Canada. Canadian's health system controls the price of drugs more effectively than the American system. In addition, America healthcare schemes such as Medicare and Medicaid are experiencing serious financial problems because of the high cost of medicines. At present, many Americans buy prescription medicines through organizations that order the medicines in Canada, where they are less expensive. This is a cause of legal disputes in the United States.

The American government seems to protect the interests of pharmaceutical companies. The pharmaceutical industry is highly profitable, and is a major exporter. It also has strong political links, and is a major donor to political campaigns. A non-governmental organization, Corporate Watch, claims that TRIPS was in fact drafted by the Pharmaceutical Research and Manufacturers of America (see Box 8).

Research conducted in 2003 shows that Australians will need to pay more for medicines because of the free trade agreement they have signed with the United States. In addition, the agreement will weaken the Pharmaceutical Benefits Scheme (Box 9).

The TRIPS framework (under the WTO) raises the costs of drugs by granting companies the right to sole production. The TRIPS-plus framework that the United States uses in bilateral trade negotiations extends the length of patent protection, and gives companies the right to 'data protection' for five years, so that they do not have to release data from drug trials. TRIPS-plus therefore affects both developing countries, such as Thailand, and developed countries such as the United States and Australia.

8. The Influence of International Drug Companies on Drug Prices

All international drug companies are based in developed countries, and most are based in the United States. These large companies produce over 90 percent of the world's drugs, and hold 97 percnet of the drug patents.

The British non-governmental organization Corporate Watch has stated that the General Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is central to the World Trade Organization, was drafted by the lobby group Pharmaceutical Research and Manufactures of America (PhRMA). Corporate Watch claims that in 2003 PhRMA spent 108.6 million dollars lobbying for favorable legislations. These legislations have a direct effect on the price of drugs and on health insurance schemes such as Medicare and Medicaid. In 2003, PhRMA employed 824 lobbyists, or over eight per senator.

The international trade in medicines is essentially controlled by only 10 companies; six of these are based in the United States. The five biggest companies of all these have revenues 2 times greater than the GNP of all countries in Sub-Saharan Africa. The journal Pharmaceutical Executive (May 2004) states that in 2003 the ten largest pharmaceutical companies had a combined revenue of 205 billion dollars, and spent 35 billion dollars on research and development. Data on the 10 biggest companies are presented below.

Rank	Company	Global revenue (billions of dollars)	Expenditure on research & development (billions of dollars)	Location of head office
1	Pfizer	39.63	7.13	United States
2	GlaxoSmithKline	29.82	4.54	Britain
3	Merck	22.46	3.17	United States
4	Johnson & Johnson	19.50	4.68	United States
5	Aventis	18.99	3.23	France
6	AstraZeneca	18.85	3.45	Britain
7	Novartis	16.02	3.07	Switzerland
8	Bristol-Myers Squibb	14.93	2.27	United States
9	Wyeth	12.62	2.09	United States
10	Eli Lilly	12.58	2.35	United States
	Total	205.42	35.98	

Source: Special report, Pharmaceutical Executive, May 2004

9. The US-Australia Free Trade Agreement Will Raise the Price of Medicines for Australians

The effect of US-Australia's free trade deal on the price of medicines in Australia is an interesting case study for Thailand.

An Australian study in 2003 found that the free trade agreement would raise the price of medicines in Australia. It also found that the Pharmaceutical Benefits Scheme (PBS), a scheme that had been effectively controlling the price of medicines for more than 50 years, would be weakened by the new rules on intellectual property.

In the past, the PBS has saved Australia 1-1.4 billion dollars a year in pharmaceutical costs. However, under the bilateral agreement between the Australia and the United States, Australia will have to pay more for its medicines.

A very interesting study looked at the effect of the free trade agreement on expenditures for five groups of drugs for which the patents were about to expire. (Three of the drugs were for reducing cholesterol, one for reducing stress, and one for asthma.) The researchers used expenditure data for the year 2003 to estimate additional expenditures in the period 2006-2009 that could be attributed to the effects of the free trade agreement. The medium estimate was 1.12 billion dollars, with a lower limit of 850 million and an upper limit of 1.56 billion. These costs, attributable to TRIPS-plus, would be born by the consumer.

Source: Lokuge, Buddhima, Faunce, T. A. and Deniss, R. 2003. A backdoor to higher medicine prices? Intellectual property and the Australia-US Free Trade Agreement. Published in http://www.tai.org.au/Whatsnew_Files/Whatsnew/Patent.pdf. Accessed date: 20/1/2005.

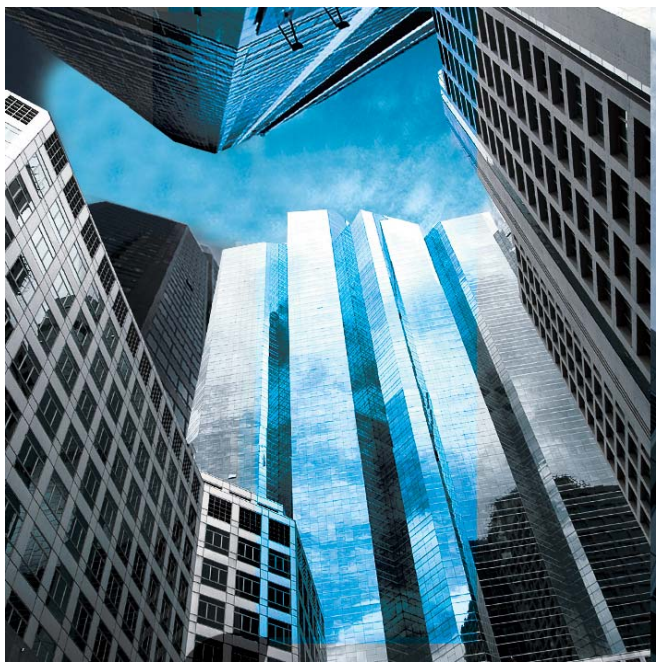
Recommendations

To some people the term 'free trade' is the ideal form of international trade. However, free trade is not necessarily fair. It can have both benefits and costs for the economy, society, and health.

Regardless of what we think about free trade, it is not something that we can avoid.

Thailand is currently negotiating free trade agreements at the multilateral, regional, and bilateral level. The number of agreements will steadily increase. Free trade agreements will become more and more important to Thailand's economy, society, and health.

Every country that enters into trade negotiations hopes to further its own interests. We need to be aware that trade negotiations have to be conducted with great care, based on precise information, and full knowledge of the costs and benefits to the country.



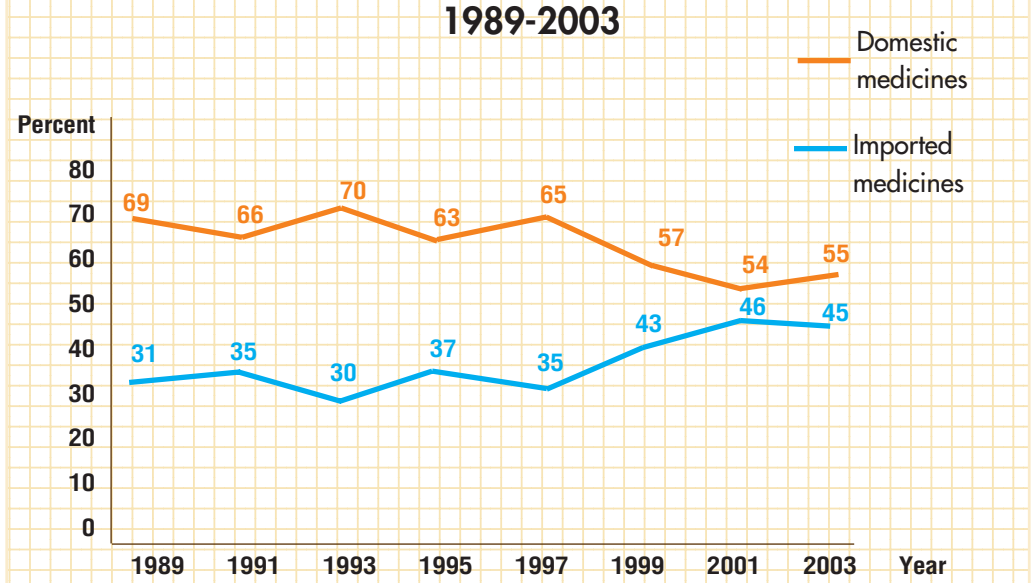
"Free trade must not raise the price of medicines to a level that people cannot afford"

Principles to consider

When looking at the effect of free trade on medicines, we need to consider the following points:

1. Free trade must not raise the price of medicines to a level that people cannot afford. Particular attention needs to be paid to the poor. If free trade raises the price of medicines, the government needs to prepare measures to offset the effects.
2. Free trade should contribute to the development of the pharmaceutical industry in Thailand, in order to reduce the money spent on imports, which have risen steadily in recent years. Over the period 1989-2003, for example, the proportion of drugs used in Thailand that were imported grew from 31 percent to 45 percent (Figure 5).

Figure 5: The source of medicines used in Thailand, 1989-2003



Source: Thai Drug Control Division, Ministry of Public Health, 2005

Medicines are different from other goods

Medicines are an unusual type of good. Unlike other goods, medicines are not something over which consumers can exercise choice. With other goods, consumers can choose the type and price. If a particular good is too expensive, consumers can look for a cheaper substitute. For instance, if bottled water is too expensive, people can drink tap water. If they cannot afford a car, they can use public transport.

Medicines are different. Neither consumer satisfaction nor price has much influence on the decision to use a particular medicine, because the decisions are mainly made by the health professionals. If a medicine that we need to use is expensive because it is patented, and if there are no cheaper substitutes, then we have to use the expensive patented medicine.

These things mean that the government must introduce measures to ensure that drug prices remain at a level that people can afford. Drug producers must not make profits so large that people's access is affected, particularly access by poor people.

Recommendations to alleviate the negative impacts from free trade negotiation

1. Conduct research on how access to essential medicines would be affected by measures proposed in bilateral trade negotiations that go beyond WTO requirements. Particular attention needs to be paid to measures proposed by the United States. Appropriate strategies to reduce the impact have to be formulated.

In bilateral trade negotiations, particularly those currently being conducted with the United States, it is very difficult for Thailand to completely turn down the requests on TRIPS-plus. It may, however, be possible to agree to only some of TRIPS-plus. The United States is Thailand's most important export market. Approximately 15-20 percent of Thailand's exports go to the United States. From the point of view of the United States, however, Thailand is only a small market. US negotiators can exploit these facts when they need to exert pressure on Thailand. This is what has happened in the past. For instance, in 1986 the United States used trade act article 301 to pressure Thailand to change many of its laws, particularly laws regarding free trade in tobacco and intellectual property rights (see Box 5).

In this situation, the most important thing for us to do is to carry out a careful study of the effect of free trade on Thai people's access to medicines. We need to find ways to alleviate the problem. If we do need to accept TRIPS-plus, we need systematic research rather than relying on anecdotes.

Many topics require further study. One important topic is the 'data exclusivity' requested by the United States. No one, particularly the drug regulatory authority, is allowed to disclose the data that the drug company used for registration, and the generic companies are also not allowed to use these data for registration of generics. Ways to avoid use of these data need to be found. When applying to register generic drugs, is it in fact necessary to use the data covered by TRIPS-plus? Forcing producers of generic drugs to conduct new clinical trials in Thailand is unethical, because it exposes participants to unnecessary risks. If there is a way of avoiding use of this data when registering medicines, then 'data exclusivity' will have little effect. Data exclusivity is requested to last five years after drug registration. This is about the time it takes Thai drug companies to discern the size of the market for the drug, to assemble raw materials, to research production methods, and to registered the generic drugs.

Another issue that deserves further study is the possibility of speeding up the registration of new drugs. The United States has called for the extension of patents from 20 to 25 years as compensation for the time spent in issuing the patent and in drugs registration. There needs to be research on how delays in issuing the patent and drug registration affect market exclusivity period. We could then negotiate for a limited form of TRIPS-plus involving reasonable compensation of loss of market exclusivity from the delay in issuing patents and drug registration. Additional strategies may also need to be proposed to further reduce the negative implications.

> “it is very difficult for Thailand to completely turn down the requests on TRIPS-plus. It may, however, be possible to agree to only some of TRIPS-plus”

to be conducted on the request to limit the use of compulsory licensing and parallel importation. This is one of the key requirements of TRIPS-plus. What problems would this requirement create? Are there any alternatives? How are we going to cope with the negative consequences?

2. Ensure that the benefits from free trade will be distributed across all groups, and that the interests of the poor will be protected

Free trade is likely to increase the country's income. This increased income should not be restricted to certain industrialists, but should be spread among all groups, so that everyone benefits from free trade. Health in particular should benefit. The government should use the extra export revenues to increase funding for health. It could collect a special tax on patented medicines and use this for pharmaceutical research and development, particularly on traditional medicines.

In addition, the government could use money earned from foreign trade to subsidize expensive medicines so that consumers benefit. People would then be able to use up-to-date medicines, even though the prices are high. The effect of free trade on access to medicines is something that can be moderated. It requires only that the health sector receives sufficient extra revenue, and that it establishes an effective health system.

3. Collaborate with other developing countries, to increase bargaining power and defend Thailand's interests

The theory of international trade is a theory of negotiation in defense of national interests. Developed countries and developing countries have different interests. The most effective way to negotiate is to closely collaborate with countries that have similar interests. Cooperating with other developing countries in multilateral negotiations is likely to increase Thailand's negotiating power, and help it defend its national interests.

On the issue of patents, cooperation between developing countries has already produced results in multilateral negotiations. In the negotiations at Doha, TRIPS was made more flexible in order to deal with matters of public health (Box 6). Cooperation may be more difficult when conducting bilateral negotiations. However, many developing countries that are negotiating bilateral agreements with the United States face similar problems regarding drug patents. This will perhaps enable developing countries to come together to persuade the United States not to go beyond the requirements set out in TRIPS, because TRIPS already gives enormous benefits to the world's biggest producer of medicines.